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Supreme Court, U.S.
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No. 98-1768

IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF THE PETITIONER

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, Virginia 22091
(703) 264-5300

September 2000

MALCOLM E. WHEELER*
WHEELER TRIGG & KENNEDY, P.C.
1801 California Street
Suite 3600
Denver, Colorado 80202
(303) 292-2525
Attorneys for Product Liability Advisory Council, Inc.

**Counsel of Record*

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

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QUESTION PRESENTED

Whether a state-court plaintiff can pursue a state-law tort claim alleging that a medical device was approved and marketed as a result of fraud on the Food and Drug Administration, or whether such a claim is impliedly preempted by the federal law governing the marketing clearance process for medical devices.

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INTEREST OF THE AMICUS CURIAE

Product Liability Advisory Council, Inc. ("PLAC") is an association of industrial companies formed for the principal purpose of submitting *amicus curiae* briefs in appellate cases involving significant issues affecting the law of product liability. Its members include manufacturers of a wide variety of products, including pharmaceuticals, medical devices, pesticides, aircraft, foodstuffs, and chemicals, who are governed by comprehensive federal safety regulations and statutes, including statutes with preemption provisions. PLAC and its members therefore have a strong interest in the proper resolution of conflicts between the requirements of federal statutes and regulations, on the one hand, and state tort law, on the other.[1]

STATEMENT

Respondent represents thousands of plaintiffs who have sued Petitioner and others for damages and equitable relief for injuries allegedly incurred as a result of surgical implantation of certain screws for spinal fixation. Some of the asserted claims charge Petitioner The Buckman Company ("Buckman") and medical device manufacturers with having defrauded the Food and Drug Administration ("FDA"). The decision below denominates these as "'fraud on the FDA' claim[s]." Pet. App. 1a.

The "fraud on the FDA" claims against Buckman do not allege that the screws were defective under product liability, negligence, or warranty principles. Nor do they allege that the devices were mislabeled in a manner on which plaintiffs or their physicians relied to plaintiffs' detriment. Rather, they allege

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[1] Letters from the parties consenting to the filing of this brief have been lodged with the Clerk of the Court. Pursuant to Rule 37.6, PLAC states that no counsel for a party has authored this brief in whole or in part and that no person or entity other than PLAC or its members has made a monetary contribution to the preparation or submission of this brief.

that (a) in applying in 1985 for FDA marketing clearance for the devices, Buckman "intentionally and falsely represented to the FDA" that the devices were "intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones"; (b) in fact, "the . . . device was intended exclusively for use in the spine"; (c) the FDA "was ignorant of the fact that these devices and device components were intended by [the defendants] to be used as pedicle screw fixation devices"; (d) the FDA would not have approved the device for marketing had it known the manufacturer's actual subjective intent; and (e) as a result of that conduct, the plaintiffs represented by Respondent suffered physical harm. Pet. App. 8a-9a.

The application in question was made pursuant to what is commonly called a "section 510(k) notification," which is provided for in the Medical Device Amendments of 1976 ("MDA") and codified at 21 U.S.C. §§ 360c(f)(1)(A)(i)-(ii) & 360e(b)(1)(B). Under that process the FDA can permit the marketing of medical devices, such as the devices in question, that are "substantially equivalent" to any device marketed before the MDA's effective date and "grandfathered in" by the MDA under 21 U.S.C. §§ 360c(f)(1)(A)(i) & 360e(b)(1)(A).

FDA regulations in effect at the time of the alleged fraud specified the information that a device manufacturer had to provide to the FDA in a section 510(k) notification. *See* 21 C.F.R. § 807.87 (1985). Those regulations did not state that the manufacturer had to notify the FDA of the manufacturer's subjective intent regarding possible post-clearance "off-label" uses to which it hoped physicians might put the device. Instead, the regulations required the manufacturer to submit written materials that the manufacturer proposed to use overtly to describe for the medical community the uses for which the device would be intended if approved by the agency – specifically, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use." 21 C.F.R. § 807.87(e) (1985).

Nevertheless, the court of appeals held that neither the MDA's express preemption provision, 21 U.S.C. § 360k, nor implied preemption principles preempted "fraud on the agency" claims alleging that, in connection with the section 510(k) notification, Buckman had deceived the FDA by not telling the agency that the manufacturer subjectively "intended [the devices] to be used" for spinal fixation, rather than "in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones." Pet. App. 8a-9a. The court of appeals thus held that a state may create and enforce a state common-law standard that makes medical device manufacturers liable for omitting from their section 510(k) notifications information not required by FDA regulations. The court further held that causation could be based upon a jury's finding, without any prior ruling or opinion by the FDA, that the agency would have withheld clearance to market the device had that information been provided.

SUMMARY OF ARGUMENT

Federal law impliedly preempts Respondent's state-law "fraud on the FDA" claims because those claims would impede the accomplishment and execution of the full purposes and objectives of Congress with respect to the MDA and its implementing regulations. The decision below permits private rights of action that are based solely on alleged violations of federal laws requiring information disclosures to a federal agency, rather than on any allegation that a product caused harm because it was unreasonably unsafe, defective, or mislabeled. It thereby permits individual states to maintain and enforce state laws that require manufacturers to provide to the FDA not only the information the FDA itself requires in determining whether to permit a device to be marketed, but additional information that state courts and juries may decide should have been provided to the FDA under their various interpretations of the MDA and FDA

regulations, even if those interpretations conflict with the FDA's own decisions.

If left intact, the decision below will foster interference with the FDA's fundamental functions of (i) determining what information should be required by the agency in deciding whether to allow new medical devices to be marketed, (ii) determining whether a particular device should be marketed, and (iii) determining what enforcement action, if any, will best serve federal policies and purposes when information required by federal statutes and regulations has not been provided to the federal agency. Such claims also would expose the FDA and other federal agencies to invasive and disruptive civil discovery.

Because the individual States historically have had no role in the formulation, implementation, or enforcement of the federal government's clearance process for medical devices, and because the formulation, implementation, and enforcement of that process historically have been solely within the province of the federal government, no "presumption against preemption" can properly be applied to limit the preemptive effect of the MDA and its implementing regulations. To the contrary, because Respondent's "fraud on the agency" claims could not even have been articulated had Congress not created the FDA, and because such claims would, if allowed, intrude into the decisions, practices, and policies of the FDA, the Supremacy Clause presumes that they cannot be maintained.

ARGUMENT

I. FEDERAL LAW IMPLIEDLY PREEMPTS RESPONDENT'S STATE-LAW "FRAUD ON THE FDA" CLAIMS.

Whether a federal law preempts a state law through the Supremacy Clause, U.S. Const. art. VI, cl. 2, is a question of congressional intent. *Northwest Cent. Pipeline Corp. v. State Corp. Comm'n*, 489 U.S. 493, 509 (1989). "Preemption may be either express or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1982) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

Implied preemption occurs when a state law conflicts with a federal law either because compliance with both would be impossible or because the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *de la Cuesta*, 458 U.S. at 153. When determining whether a state law stands as an obstacle to the accomplishment of congressional purposes and objectives, courts "examin[e] the federal statute as a whole and identif[y] its purpose and intended effects." *Crosby v. National Foreign Trade Council*, 120 S. Ct. 2288, 2294 (2000). Even if the federal and state laws have common purposes and goals, federal law still preempts state laws that would impair the federal law's methods of achieving those goals: "The fact of a common end hardly neutralizes conflicting means." *Id.* at 2297-98. *Accord International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) ("A state law is also preempted if it interferes with the methods by which the federal statute was designed to reach this goal.").

Under these principles, Respondent's state-law "fraud on the FDA" claims are impliedly preempted both because they would impede the fulfillment of the MDA's purposes and objectives and because they would interfere with the federally selected methods for accomplishing those purposes and objectives. Those claims would contravene Congress's intent not to allow private actions for violations of FDA regulations. They would contravene Congress's intent to have the FDA decide, in accordance with the requirements specified in the MDA, the bases on which applications to market new medical devices should be evaluated and decided. They would contravene Congress's intent to have the FDA decide how and under what circumstances to enforce FDA regulations requiring disclosure of information to the agency. They would undermine the finality of FDA de-

terminations as to which medical devices should be made available to physicians and their patients. And they would subject the FDA and other federal agencies to interference with regulatory tasks by invasive discovery requests from private parties in civil litigation throughout the country.

A. The Court of Appeals' Decision Undermines Congress's Intent Not to Create a Private Right of Action for Violations of FDA Regulations.

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996), this Court held that no private right of action exists under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the MDA. Accordingly, in its decision below, the court of appeals acknowledged that it is "well established that Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA." Pet. App. 13a. *Accord* Pet. App. 25a. The court emphasized that it did not conclude that "any of the plaintiffs have stated a claim under the FDA's regulations." Pet. App. 25a. Instead, it stated, Respondent's "fraud on the FDA" claims tracked the elements of common-law fraudulent misrepresentation and were "based on state rather than federal law." Pet. App. 9a. As described by the court, common-law fraudulent misrepresentation requires (i) a representation of fact, opinion, intention, or law; (ii) knowledge of its falsity; (iii) intent to induce reliance; (iv) justifiable reliance; and (v) resulting injury. *See* Pet. App. 9a.

Application of those elements to the "fraud on the FDA" claims in this litigation reveals, however, that, even if written as common-law claims, the claims actually constitute an attempt by private parties to seek damages, and impose monetary penalties, for alleged violations of FDA disclosure regulations as interpreted by state courts and juries. The plaintiffs here do not allege that Buckman made any false representation to them or their physicians, and they do not allege that they justifiably relied on any representation by Buckman. *See* Pet. App. 8a-9a. Rather, they allege that their injury resulted from Buckman's alleged deception of the FDA. Thus, as noted by the dissent below, the "fraud on the agency" claims create, in effect, a private right of action for violations of FDA disclosure regulations. *See* Pet. App. 28a (Cowen, J., dissenting).

FDA regulations specify the information that manufacturers must provide in their section 510(k) notifications. *See* 21 C.F.R. § 807.87. The regulations require, among other things, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use." 21 C.F.R. § 807.87(e). Thus, the regulation requires the manufacturer to provide proposed labeling stating the use that will be overtly represented to physicians as the use for which the device is intended. It does not require the manufacturer to submit any separate declaration of any subjective, hoped-for off-label uses that might occur if the FDA should approve the section 510(k) notification and allow the device to be marketed.[2]

The FDCA and the MDA authorize the federal government to enforce, and penalize violations of, their provisions, including provisions that prohibit the making of false or misleading statements to the FDA, the use of false or misleading labeling or advertising, and the failure to provide to the FDA information required by the statutes. *See* 21 U.S.C. §§ 337 (providing for enforcement proceedings by federal government), 331(a)-(b) (prohibiting misbranding of medical devices), 352(a) (defining misbranding to include labeling that "is false or misleading in any particular"), 331(q)(2) (prohibiting submission to FDA of any required report that is "false or misleading in any respect"), 331(w) (prohibiting knowingly false statements to FDA), 352(t)

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[2] The regulations elsewhere provide that the "intended uses of an article may change *after* it has been introduced into interstate commerce," and the labeling must be made adequate for such other uses for a device that has already been "*introduced* into interstate commerce." 21 C.F.R. § 801.4 (emphasis added).

(defining misbranding to include failure "to furnish any material or information required by or under section 360i of this title respecting the device"). The statutes provide the federal government with a wide variety of sanctions and enforcement mechanisms. *See, e.g.*, 21 U.S.C. §§ 333(a) (criminal penalties), 332 (injunctions), 333(f)(1) (civil monetary penalties), 334 (seizure), 360h(e) (recall), 360e(e)(C) (withdrawal of approval to market, if "the application contained or was accompanied by an untrue statement of a material fact").

Congress made clear its intent that enforcement of these laws must be by the federal government: "Except as provided in subsection (b) of this section, all such proceedings for the enforcement . . . of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Congress could have included in the exceptions a provision allowing private rights of action for fraud on the FDA, but it did not do so. *See* 21 U.S.C. § 337(b).

Respondent's "fraud on the FDA" claims conflict with this extensive statutory scheme. Though purporting to be state-law fraud claims, they in fact depend entirely on alleged violations of federal statutes and regulations requiring that certain information be disclosed to the FDA. Respondent concedes as much in its brief in opposition to the petition for a writ of certiorari:

> The basis for plaintiffs' fraud claim is that Buckman and others defrauded the FDA by making false statements to the agency concerning an issue of paramount *regulatory concern* – the intended use of AcroMed orthopedic plates and screws. Thus, *plaintiffs seek recovery for conduct which violates federal law*.

Brief in Opposition to Petition for a Writ of Certiorari 18 (emphasis added). If Congress had not created the FDA, and if the FDA had not promulgated its regulation requiring manufacturers to submit "[p]roposed labels, labeling, and advertisements sufficient to described the device, its intended use, and the directions for its use," it would have been literally impossible for plaintiffs

to have alleged this "fraud on the FDA" claim. Allowing such a claim, therefore, would not preserve any historically available state-law claim. Instead, it would grant plaintiffs a new private right of action based solely on federal regulations promulgated and enforced by a federal agency to promote federal purposes and objectives.

Moreover, unlike the sweeping preemption rejected by this Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), preemption of "fraud on the FDA" claims such as those asserted by Respondent here would not bar "most, if not all, relief for persons injured by defective medical devices." *Id.* at 487. To the contrary, disallowing a private action seeking monetary relief based on alleged violations of FDA disclosure regulations would not prevent any person injured by a defective or mislabeled device from seeking redress under any of several traditional state-law theories. *Lohr* instructs, for example, that plaintiffs may pursue state-law claims based on design defects, manufacturing defects, or inadequate warnings. 518 U.S. at 494, 501-02. They also may seek relief for fraudulent statements allegedly made to themselves or their physicians, or for claims based on breaches of express and implied warranties.

Although not a "fraud on the FDA" case, *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981), is instructive because it focuses on the disruption to agencies that private, state-law tort claims can cause. The Court there considered whether a state-law damages action "may be asserted against a regulated carrier when the [Interstate Commerce] Commission has approved its decision to abandon the [railroad] line in question." 450 U.S. at 313. The Court observed that the Commission's authority to decide whether to allow carriers to abandon existing railroad lines was "critical to the congressional scheme, which contemplates comprehensive administrative regulation of interstate commerce," and "[i]n deciding whether to permit an abandonment, the Commission must balance 'the interests of those now served by the present line

on the one hand, and the interests of the carrier and the transportation system on the other.'" *Id.* at 321 (citation omitted). The Court concluded that the agency's determinations were not susceptible to judicial "redecision" because "[t]he breadth of the Commission's statutory discretion suggests a congressional intent to limit judicial interference with the agency's work." *Id.* The Court therefore held that state-law damages actions were impliedly preempted because they would, if allowed, conflict with federal purposes. *Id.* at 326.

Here, as in *Kalo Brick*, (i) the FDA's authority to decide whether, and based on what information, to allow new medical devices to be marketed is "critical to the congressional scheme"; (ii) in deciding whether to permit a new device to be marketed, the FDA must balance the need to ensure safety with the interests of patients who will benefit from greater availability of, and lower prices for, medical devices that otherwise would be restricted to "grandfathered" devices with little or no competition; and (iii) the breadth of the FDA's rulemaking and enforcement powers, combined with Congress's clear intent to preclude private causes of action, "suggests a congressional intent to limit judicial interference with the agency's work." State-law actions that not only second-guess the FDA's decisions, but do so based on a theory that the FDA should have received additional information and would have reached a different decision had it received the additional information, constitute the type of "interference with the agency's work" that *Kalo Brick* held must be preempted.

Because the "fraud on the FDA" claims asserted by Respondent conflict with Congress's intent not to create a private right of action under the MDA, and would interfere with Congress's method of giving the FDA authority to decide what actions to take if required information has not been provided, those claims are preempted by the MDA and its implementing regulations.

B. Respondent's State-Law "Fraud on the FDA" Claims Would in Effect Alter the Disclosure Requirements Established by the FDA for Section 510(k) Notifications.

The FDA reviewed Buckman's section 510(k) notification materials, found that they provided the information required by the MDA and its implementing regulations, and determined that the devices could lawfully be marketed. *See* Pet. App. 5a. Respondent's "fraud on the FDA" claims attempt to override those FDA decisions. Respondent's claims ask state courts and juries to conclude that Buckman should have provided the FDA with information about the manufacturer's alleged subjective hope that, despite the approved, uniform statements of intended use on the devices' labeling and advertising, the entire orthopedic community would put the devices only to off-label uses. Those claims also ask state courts and juries to conclude that, if Buckman had stated such a subjective hope, the FDA would not have allowed the devices to be marketed in competition with the "grandfathered" devices to which the FDA found the new devices "substantially equivalent." Under Respondent's theory, if any court or jury so concludes, the manufacturer may be liable in damages, even though (i) the FDA approved the application, (ii) the FDA has not found the devices to be mislabeled, (iii) the FDA subsequently reviewed evidence submitted by Respondent and stated that the FDA "does not believe that pedicle screw spinal systems present a substantial deception or an unreasonable and substantial risk of illness or injury," 63 Fed. Reg. 40025, 40035-36 (July 27, 1998), and (iv) Respondent has not alleged that the devices are defective, unreasonably dangerous, or mislabeled, or that any false or misleading statement was made to plaintiffs or their physicians.

If the decision below stands, device manufacturers submitting subsequent 510(k) notifications to the FDA will tend not to provide the FDA only with information the FDA itself requires; rather, manufacturers will be induced to try to predict what

courts and juries in the various States might in later years decide the FDA should have been provided and would have considered dispositive if the information had been provided. Manufacturers will likely burden the FDA with information they think juries might some day decide the FDA should have been provided, regardless of whether the FDA in fact required that information.

The pertinent regulation governing section 510(k) notifications, 21 C.F.R. § 807.87, did not require disclosure of the manufacturer's subjective intent regarding how it hoped physicians might use its device off-label. Even the regulation governing post-clearance developments, 21 C.F.R. § 801.4, defined "intended uses" as "the *objective intent* of the persons legally responsible for the labeling of devices." 21 C.F.R. § 801.4 (1985) (emphasis added). That post-clearance intent "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." *Id.* A device's intended uses "may change after it has been introduced into interstate commerce by its manufacturer"; if they do, the seller "is required to supply adequate labeling in accordance with the new intended uses." *Id.* Thus, even the post-clearance regulation focuses on the applicant's initial "objective intent," recognizes that "intended uses" may change over time as a manufacturer gains knowledge, rather than speculative hopes, about *actual* use in the medical community, and requires corresponding changes in the labeling under those circumstances.

The MDA prohibits manufacturers from advertising or otherwise marketing devices for off-label uses. *See* 21 U.S.C. §§ 321(n), 331(a)-(b). It authorizes the FDA to enforce that prohibition by, among other actions, withdrawing its clearance for marketing of a device if the manufacturer markets the device for an off-label use. *See* 21 U.S.C. § 360e(e). The FDA may require additional labeling if it determines that a manufacturer's devices are being used off-label in a manner that requires such additional labeling. *See* 21 C.F.R. § 801.4. Neither the MDA nor its implementing regulations contain a provision, however,

for the agency to withdraw its marketing clearance if it should learn that, when the manufacturer submitted its section 510(k) notification, the manufacturer harbored a subjective hope or belief that physicians would put the device only to off-label uses once the device received marketing clearance from the FDA.

Accordingly, Plaintiffs' "fraud on the FDA" claims would alter the FDA's definition of "intended use" for section 510(k) notifications, alter the section 510(k) notification requirements, and undermine the FDA's decisions as to which medical devices should be allowed on the market and with what labeling. The claims would use state law to penalize conduct that federal law permits. *Cf. Crosby v. National Foreign Trade Council*, 120 S. Ct. 2288, 2296-97 (2000) (noting that the challenged state statute "conflicts with the federal law at a number of points by penalizing individuals and conduct that Congress has explicitly exempted or excluded from sanctions," and holding the state law preempted).

Such state-law revisions of federal requirements would endanger federal objectives and create substantial uncertainties in the approval process. The decision below, for example, emphasizes that Respondent's representative complaint alleges that the manufacturer subjectively intended the device to be "exclusively for use in the spine" when they filed their section 510(k) notification. Pet. App. at 8a. Under that rationale, could a "fraud on the agency" claim likewise proceed if a manufacturer secretly hoped or believed that 90%, rather than 100%, of post-clearance sales of a new medical device would be for off-label use in spinal surgery? Would a hope or belief of 50% suffice to state a claim? Would it make any difference if the manufacturer subjectively hoped or believed that the off-label use would be minimal at first, but build over a period of time? Would it make any difference if, when the manufacturer filed its section 510(k) notification, it subjectively hoped or believed that off-label uses would occur post-clearance, but it changed its mind before clearance was granted? If it changed its mind the day after

clearance was granted? Would federal policies and purposes be rationally served by allowing "fraud on the agency" claims if the subjective intent was formed one week before clearance was granted, but not if the subjective intent was formed one week after clearance was granted, especially if, as here, there is no claim that the device is defective, unreasonably dangerous, or mislabeled?

If there is to be a disclosure requirement pertaining to some subjective intent at the time a section 510(k) notification is filed, all of these are questions that the federal agency charged by Congress with the responsibility for promulgating and enforcing the regulations, not courts and juries in all the States, should answer. The agency knows what information it needs and wants, and its decision should not be displaced by a hodgepodge of decisions by state courts and juries. The agency knows what information is important enough to warrant enforcement proceedings, or an order requiring labeling changes, when information it requires is withheld or misrepresented. And the agency knows what balance it seeks to strike between ensuring informed decision-making and imposing penalties that might impair competition, cause the public to be deprived of certain products, cause the prices of medical devices to increase, or induce regulated entities to burden the agency with unwanted information in order to avoid such penalties in the future.

The agency is also uniquely capable of promulgating uniform standards. State-imposed disclosure requirements would vary, not only because jury verdicts would differ, but also because state-law fraud doctrines are not uniform. Because of differences in substantive state fraud laws, device manufacturers, if threatened with state-law "fraud on the agency" claims, would tend not only to satisfy the FDA's requirements for section 510(k) applications, but also to survey state laws and submit to the FDA materials that courts and juries in any of the 50 states might conclude should be submitted to the FDA.

For these reasons, state-imposed requirements penalizing manufacturers with damages awards in private actions for not disclosing their subjective hopes when section 510(k) notifications are filed would impermissibly conflict with the federally selected method of introducing new devices to the market. *See International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) ("[I]t is not enough to say that the ultimate goal of both federal and state law is [the same]. A state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal."). As the United States has noted, "[D]uties concerning the submission of information to a federal agency are, at least as a general matter, appropriately defined and enforced by the federal government." Brief for the United States as *Amicus Curiae* in Support of the Petition 15. State courts and juries should not be permitted to substitute their own varying views of disclosure requirements for the uniform requirements that the FDA has promulgated to promote federal purposes and objectives.

C. The Decision Below Would Upset the FDA's Balance Between Keeping Unsafe or Ineffective Devices off the Market and Allowing Physicians to Use Devices for Innovative Off-Label Purposes.

The FDA neither controls the practice of medicine nor interferes with physicians' judgment about how to use a lawfully marketed device. In a statement to a House subcommittee, Michael Friedman, the FDA's Deputy Commissioner for Operations, testified:

> The history of the FDC Act indicates Congress did not intend FDA to interfere with the practice of medicine. Thus, once a product is approved for marketing for a specific use, FDA generally does not regulate how, and for what uses, physicians prescribe that drug.... FDA recognizes that, in certain circumstances, off label uses of approved products are appropriate, rational, and accepted medical practice. Off label uses, particularly for oncology, rare diseases, and

> pediatrics, can be of great value. Some off label uses have been of great historical importance. Use of beta blockers in hypertension and angina preceded labeling for these uses by many years. It is inevitable that there will be preliminary support for off label uses before definitive information becomes available. Physicians confronted with patient needs, may choose to act on such data, especially where there are no good alternatives.

Michael Friedman, *Misuse of Prescription Drugs*, Statement to the Subcommittee on Human Resources and Intergovernmental Relations Committee on Government Reform and Oversight, 1996 WL 10830744, at *5 (Sept. 12, 1996).

The FDA has recognized the importance of physicians' ability to use prescription medical products off-label: "Such 'unapproved' or, more precisely, 'unlabeled' uses may be appropriate and rational in certain circumstances, and may in fact, reflect approaches to drug therapy that have been extensively reported in medical literature." *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bulletin 4 (Apr. 1982). The American Medical Association estimates that 40 to 60 percent of all prescriptions in the United States are written for drugs to be used for a purpose other than their FDA-approved purpose. Veronica Henry, *Off-Label Prescribing: Legal Implications*, 20 J. Legal Med. 365, 365 (1999) (citation omitted). Indeed, in some fields of medicine, off-label use has become the standard of care. In 1995, for example, the FDA recognized that, since 1992, pedicle fixation with bone screws had constituted the standard of care in the surgical community. *See Proposed Rules: Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems*, 60 Fed. Reg. 51946, 51947 (1995). In short, off-label uses of medical devices are a "valuable part of the practice of medicine." Pet. App. 29a (Cowen, J., dissenting).

The FDA is well aware of its duties regarding the possible harm resulting from off-label uses. It has established strict requirements to prevent companies from using marketing practices to promote off-label uses. *See, e.g.*, 21 U.S.C. § 360aaa. If a manufacturer wants to market a device for what is currently an off-label use, the manufacturer must apply for FDA approval to market for that use. *See* 21 U.S.C. § 360e(d)(6)(A); Friedman, *Misuse of Prescription Drugs*, 1996 WL 10830744, at *7-8. And, as already noted, the FDA's regulations require that if, after a device has been introduced into interstate commerce, it is used for purposes other than the ones for which the manufacturer offers it, the manufacturer must "provide adequate labeling for such a device which accords with such other uses . . . ." 21 C.F.R. § 801.4. The FDA thus has struck the balance it has concluded is necessary to ensure the safety and effectiveness of medical devices and to foster appropriate innovative uses of those devices by physicians.

Respondent seeks to use state tort laws to impose a different balance. Specifically, Respondent seeks to make the balance turn not on the objective factors of (i) the use stated in the device's labeling, (ii) uses to which the device is actually put once on the market, and (iii) the device's safety and effectiveness for those uses as determined by the FDA's experts, but instead on the subjective question of whether, when the manufacturer submitted its 510(k) notification, the manufacturer harbored a hidden hope that the device would be used exclusively for an off-label purpose. Then, Respondent seeks to use state tort laws in private lawsuits to impose monetary penalties, collected by private plaintiffs, not because the device was defective or unreasonably dangerous when put to the off-label use, and not because the device was mislabeled in a manner on which plaintiffs or their physicians relied, but simply because the manufacturer did not initially disclose its subjective intent to the FDA.

Respondent's state-law "fraud on the FDA" claims would thus impair the FDA's method and goal of striking a balance between ensuring the safety and effectiveness of medical devices and not unduly restricting the medical community's inno-

vative uses of medical devices in the exercise of physicians' medical judgment. For that reason, such claims are impliedly preempted.

D. Respondent's "Fraud on the FDA" Claims Would Expose the FDA to Burdensome Discovery in Private Litigation Throughout the Country.

The decision below also would interfere with the FDA's purposes, objectives, and methods by subjecting the agency to discovery requests by private litigants asserting "fraud on the FDA" claims. Such discovery requests would intrude into the FDA's deliberations and decisions and divert the agency's attention and resources from the task of performing regulatory functions to the task of responding to discovery requests.

Nor would the FDA be the only federal agency subject to such intrusions and diversions. Under Respondent's theory, any federal agency responsible for regulating an industry would be vulnerable to a flood of discovery requests in private lawsuits in which plaintiffs assert "fraud on the agency" claims against the regulated entities.

The burden on federal agencies could be substantial. Plaintiffs are likely to seek discovery to prove (i) that the agency intended its regulations to mean what the plaintiffs contend they mean, (ii) that the agency relied on the allegedly fraudulent statement, and (iii) that the agency would have taken some different action with respect to the device had it received the information the plaintiffs claim it should have received. Defendants are likely to seek additional discovery to prove (iv) that the agency did not intend to require the information that plaintiffs contend was fraudulently withheld, (v) that, whatever the agency's intent, the agency did not consider the information material to safety determinations, and (vi) that the agency would not have taken any different action had it received the information the plaintiffs claim it should have received. In this case, for

example, defendants would want to obtain from the FDA all agency documents showing that FDA officials knew and understood, from their review of the defendants' previous section 510(k) filings, that the defendants hoped physicians would use the device "off-label" for spinal fixation surgery, that the "grandfathered" devices on which the defendants' section 510(k) notifications were based had been used off-label in numerous instances for spinal fixation, and that agency officials knew of the prevalence of such off-label uses.

The burden of responding to such discovery requests – even if the agency's responses were repeated refusals to produce documents or deponents – could be substantial. This multidistrict litigation alone, for example, involves more than 2,000 individual actions that may be tried in various jurisdictions. *See* Pet. App. 1a. And this litigation involves only orthopedic screws. If the likely discovery here were to be multiplied by the number of other medical devices or drugs that could become the subject of "fraud on the FDA" actions, and by the number of potential lawsuits alleging fraud on other federal agencies, the draining of agency resources, diversion of agency attention from regulatory duties, and alteration of internal decision-making processes would be staggering.

In sum, "fraud on the FDA" claims would obstruct congressional objectives in several ways. They would impose new disclosure requirements on section 510(k) notifications, burdening the FDA with information it did not want. They would alter manufacturers' behavior in submitting materials to the FDA and proposing devices for marketing as "substantially equivalent" to predicate devices. They would impair the FDA's chosen method of balancing physicians' innovative off-label uses against the need to ensure the safety and efficacy of marketed devices. And they would expose federal agencies to repeated, burdensome civil discovery that interferes with the agencies' regulatory functions. Because "fraud on the FDA" claims would erect these obstacles to the achievement of federal pur-

poses and objectives, and interfere with the methods chosen by Congress and the FDA to achieve those purposes and objectives, they are impliedly preempted.

II. BECAUSE THE REGULATION OF MEDICAL DEVICES IS NOT WITHIN THE STATES' HISTORICAL POLICE POWERS, NO PRESUMPTION AGAINST PREEMPTION SHOULD APPLY TO THIS CASE.

In summarizing its reasons for concluding that Respondent's "fraud on the FDA" claims survived preemption, the court of appeals below relied on a "presumption against preemption." Pet. App. 18a. It erred in doing so. Although this Court has applied a presumption against preemption in some circumstances, no such presumption can properly be applied here, where the federal government has a strong and well-established interest in uniform regulation and the regulation in question has not historically fallen within the States' police powers.

This Court's articulation of a presumption against preemption of state law has occurred primarily in cases "in which Congress has 'legislated . . . in a field which the States have traditionally occupied . . . .'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting, *inter alia*, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). *Accord CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993); *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 206 (1983). In other contexts the Court often has conducted its preemption analysis without employing the presumption at all. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 545-46 (1992) (Scalia, J., concurring in the judgment in part and dissenting in part) (citing *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992), and *Norfolk & W. R.R. Co.*

v. American Train Dispatchers Ass'n, 499 U.S. 117, 129 (1991)).[3]

The Court's recent preemption decisions show the limited applicability of such a presumption. In *United States v. Locke*, 120 S. Ct. 1135, 1147-48 (2000), the Court construed the presumption narrowly, stating that "an 'assumption' of nonpreemption is not triggered when the State regulates in an area where there has been a history of significant federal presence." One month later the Court applied no such presumption before concluding that federal railroad statutes and regulations preempted a state wrongful-death action. *Norfolk S. Ry. Co. v. Shanklin*, 120 S. Ct. 1467 (2000). Still more recently the Court held, without applying any presumption against preemption, that federal law preempted the plaintiffs' state-law tort claim. *Geier v. American Honda Motor Co.*, 120 U.S. 1913 (2000). And in *Crosby v. National Foreign Trade Council*, 120 S. Ct. 2288 (2000), the Court indicated that the presumption is unnecessary in an "obstacle preemption" case: "Assuming, arguendo, that some presumption against preemption is appropriate, we conclude, based on our analysis below, that the state Act presents a sufficient obstacle to the full accomplishment of Congress's objectives under the federal Act to find it preempted." *Id.* at 2294 n.8. These decisions confirm that the presumption against pre-

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[3] Cases other than those cited by Justice Saclia in *Cipollone* in which the Court disregarded any presumption against preemption abound. *See, e.g., American Airlines, Inc. v. Wolens*, 513 U.S. 219 (1995); *FMC Corp. v. Holliday*, 498 U.S. 52 (1990); *Louisiana Pub. Serv. Comm'n v. Federal Communications Comm'n*, 476 U.S. 355 (1986); *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202 (1985); *Brown v. Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491 (1984); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984); *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982); *Malone v. White Motor Corp.*, 435 U.S. 497 (1978); *United States v. Shimer*, 367 U.S. 374 (1961); *McDermott v. State of Wisconsin*, 228 U.S. 115 (1913).

emption is narrow in scope and must be closely cabined to prevent it from undermining the mandate of the Supremacy Clause.

The presumption is especially inapplicable here. This case focuses on the scope and enforcement of *federal* regulations pertaining to medical devices – an area firmly under the control of a federal agency and subject to an extensive federal regulatory scheme. *Cf. Locke*, 120 S. Ct. at 1148 (noting Congress's historical legislation of maritime commerce and its "extensive federal statutory and regulatory scheme," and declining to apply an assumption of non-preemption). Not only are the scope and enforcement of federal regulations historically in an "area where there has been a history of significant federal presence," *id.* at 1147-48, but the individual States have had no historical role whatsoever in regulating what information is required to be provided to the FDA, and no such area has been "traditionally occupied" by the States. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The history of federal presence and the lack of state involvement dictate that no presumption against preemption can properly be applied here.

A presumption against preemption is further inapplicable because of the established principle that state law must yield to federal law when, as here, a state law does interfere with federal law. As this Court has stated:

> The relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that the federal law must prevail. Article VI, Clause 2. This principle was made clear by Chief Justice Marshall when he stated for the Court that *any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.*

Free v. Bland, 369 U.S. 663, 666 (1962) (emphasis added)(quoted with approval in *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)); *Brown v. Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468

U.S. 491, 503 (1984); *Gade v. National Solid Wastes Mgt. Ass'n*, 505 U.S. 88, 108 (1992) (plurality opinion) (even if a State has a "compelling interest," the Supremacy Clause requires that "any state law . . . clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield"). Indeed, the Court has applied what amounts to a presumption *in favor of* preemption in cases where the interest in federal primacy and uniformity is well-established. *See, e.g., Hines v. Davidowitz*, 312 U.S. 52, 63, 68 (1941) (foreign relations and regulation of aliens); *Allen-Bradley Local No. 1111 v. Wisconsin Employment Relations Bd.*, 315 U.S. 740, 749 (1942) (same); *cf. Brown*, 468 U.S. at 502-503 (recognizing "presumption of federal preemption" in areas within the primary jurisdiction of the NLRB). This reflects the common-sense conclusion that, in a field long and thoroughly dominated by federal statutes and interests, Congress is unlikely to enact statutes that allow state laws to intrude on and conflict with the purposes and methods of the federal statutes.

Even when a State's tort law is advanced as a means of exercising the States' historical police power to safeguard their citizens' health or safety, it cannot save from preemption a state-imposed duty that conflicts with a federally-imposed duty. In *Boyle v. United Technologies Corp.*, 487 U.S. 500, 509 (1988), the Court noted that a state-imposed duty of care regarding the design of a product would conflict with the design duty imposed on the manufacturer under its contract with the federal government. The state-law duty undeniably concerned a critical issue of health and safety – namely, whether a pilot's family could recover damages from a helicopter manufacturer after a design defect in a helicopter's escape hatch allegedly caused the pilot's death. Nonetheless, the Court held the state tort claim preempted. *Id.* at 511-12.

Accordingly, this is not a proper case in which to apply a presumption against preemption. Even if the Court were to consider such a presumption, the presumption could not prevent

preemption here, because the federal government historically has determined the scope and enforcement of its own regulations regarding the information to be provided to the FDA, and this area of law does not implicate any historical police power of the States.

CONCLUSION

Because federal law preempts Respondent's state-law "fraud on the FDA" claims, the judgment of the court of appeals should be reversed.

Respectfully submitted,

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, Virginia 22091
(703) 264-5300

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MALCOLM E. WHEELER*
WHEELER TRIGG & KENNEDY, P.C.
1801 California Street
Suite 3600
Denver, Colorado 80202
(303) 292-2525
Attorneys for Product Liability Advisory Council, Inc.

**Counsel of Record*